7. 510(k) Summary Information

JUL - 3 2007

In accordance with 21 CFR 807.92, the 510(k) Summary is presented to provide an understanding for the basis of substantial equivalence.

7.1 Submitter's & Owners Name and Address

Arthur B. Flick MD
Medical Molecular Therapeutics LLC
36 Lake Rabun Road
Lakemont, Georgia 30552

Contact Person: Arthur B. Flick MD
Telephone: 706 782 5064
Email: abflick@alltel,net

7.2 Date Prepared

20 September 2006

7.3 Device Name

Trade Name:	Silvion Antibacterial Silver Skin & Wound Moisturizing Solution
Common Name:	Skin & Wound Moisturizing Solution
Classification Name:	Liquid Bandage KMF

7.4 Predicate Devices 807.92(a)(3)

Dermacyn Wound Cleanser	K 042729
Saline Solution (Wound Dressing)	K040683
Restore Wound Cleanser	K022670
Dermacyn Wound Irrigation	K042729

X-Static Silverseal Hydrogel Wound Dressing	K040019
Acryderm Silver Antimicrobial Wound Gel	K011994
Antimicrobial Barrier Wound Contact Dressing	K023612

7.5 Device Description

A buffered ionic silver aqueous wet dressing for external wound management. The product provides a moist environment that aids the body in the healing process. The non-irritating components of Silvion Antibacterial Silver Skin & Wound Moisturizing Solution allow the product to be used on mucous membranes, the skin as well as acute and chronic wounds. The silver provides effective protection of the solution against microbial contamination. The Silvion Antibacterial Silver Skin & Wound Moisturizing Solution is clear, odorless and colorless. The product is available in 2 oz, 4 oz, 8 oz and 16 oz spray bottles.

7.6 Assessment of Performance Data

Silvion Antibacterial Silver Skin & Wound Moisturizing Solution has been subject to *in vitro* and *in vivo* biocompatibility (ISO Modified Intracutaneous Study, the USP and ISO Modified Systemic Toxicity Study and the ISO Maximization Sensitization) and cytotoxicity testing (Agarose Overlay Method). These tests support the safe use of Silvion Antibacterial Silver Skin & Wound Moisturizing Solution in contact with breached or compromised skin. *In vitro* antimicrobial testing was assessed by the standard the MIC and MBC Dilution Methods, Zone of Inhibition, USP Antimicrobial Effectiveness Test <51>, USP Microbial Limit Test <61>, Bioburden Aerobic Total Count and Microbial Challenge Test.

7.7 Statement of Intended Use

OTC: Minor burns, abraded skin, irritated areas minor wounds.

Professional: Stage I-IV pressure ulcers, stasis ulcers, foot ulcers, diabetic ulcers, post surgical wounds, first and second degree burns, abrasions and skin irritations.

7.8 Technological Characteristics and Substantial Equivalence

Silvion Antibacterial Silver Skin & Wound Moisturizing Solution is a combination product within the meaning of section 503(g) of the Federal Food, Drug, and Cosmetic Act (Act) and Title 21 of the Code of Federal Regulations (CFR) section 3.2(e)(1) and (2). In accordance with section 503(g)(1) of the Act and 21 CFR section 3.4, Silvion Antibacterial Silver Skin & Wound Moisturizing Solution had two modes of action. One action of the product is the device components' action to provide moisture to dermal wounds and inflamed skin. Another mode of action of the product is that of the drug component (ionic silver) to act as an antimicrobial agent. The primary mode of action of the combination product is attributable to the device components' action to provide moisture to dermal wounds and inflamed skin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medical Molecular Therapeutics LLC
% Arthur B. Flick, MD
36 Lake Rabun Road
Lakemont, Georgia 30552

JUL - 3 2007

Re: K063063
Trade/Device Name: Silvion™ Antibacterial Silver Skin & Wound Moisturizing Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 22, 2007
Received: May 24, 2007

Dear Dr. Flick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. INDICATIONS FOR USE

510(k) Number: K063063/S1

Device Name: Silvion™ Antibacterial Silver Skin & Wound Moisturizing Solution

Indications For Use:

Over-The-Counter Indications:

For minor burns, abraded skin, irritated areas and minor wounds.

Professional Prescription Indications:

Wound moistening solution for dermal lesions such as Stage I-IV pressure ulcers, stasis ulcers, foot ulcers, diabetic ulcers, post surgical wounds, first and second degree burns, abrasions and skin irritations.

Prescription Use X AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K063063